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Re-evaluation Note REV2013-13

Re-evaluation Project Plan for Chlorimuron Ethyl

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In Canada, chlorimuron ethyl is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrants of chlorimuron ethyl were notified of the initiation of the re-evaluation of chlorimuron ethyl. Following this, the registrants of chlorimuron ethyl technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of chlorimuron ethyl.

Chlorimuron ethyl is an herbicide that has been registered in Canada since 1996. Chlorimuron ethyl is currently registered for control of broadleaf weeds in soybean crop (Terrestrial Feed and Food Crops [Use-Site Categories 13 and 14] and Industrial Oil Seed Crops and Fibre Crops [Use-Site Category 7]). Registered chlorimuron ethyl end-use products are formulated as wettable granules, to be applied by ground equipment only.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of chlorimuron ethyl, as well as additional data required. Should additional information become available during the re-evaluation period that affects the regulatory status of chlorimuron ethyl, the PMRA will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for chlorimuron ethyl is anticipated to be published in 2016.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for chlorimuron-ethyl was considered complete at the time of initial registration and no major updates have been made since then. Data generated since the time of the original submission (acute and short term neurotoxicity studies, immunotoxicity study, short term dermal toxicity study) or that have been requested (short-term inhalation study) that may impact the hazard assessment, will be evaluated. Verification of the points of departure used for occupational and dietary risk assessment will be undertaken and areas not addressed in the original evaluation (for example, assessment of acute reference dose requirement, application of the PCPA factor) will be reviewed. Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

The occupational and residential exposure database is considered complete and no data are required at this time. An update to the occupational risk assessment will be required if toxicity endpoints change and a quantitative post-application assessment will be conducted.

The residue chemistry database for the dietary risk assessment is considered to be complete and no data are required at this time. The dietary exposure and risk assessment previously conducted to support the registered uses will be verified to ensure they continue to meet current science standards and approaches. The dietary exposure assessment will be updated to reflect current data including new food consumption data, as well as any revised reference doses (acute reference dose and acceptable daily intake), if applicable.

Environmental Risk Assessment

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements and the Toxic Substances Management Policy will be considered.

Value

The value of chlorimuron ethyl will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology have been identified for chlorimuron ethyl and were requested from the technical registrants (Appendix I).

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for chlorimuron ethyl is anticipated to be published for consultation in 2016.

Additional Information

PMRA documents can be found in the Pesticides or Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Chlorimuron Ethyl

DACO 4.3.5	Short-term Dermal (21/28-day)
DACO 4.5.12	Acute Neurotoxicity (rat)
DACO 4.5.13	90-day Neurotoxicity (rat)
DACO 4.8	Other Studies/Data/Reports (immunotoxicity study)
DACO 4.3.6	Short-Term (90-day) Inhalation study.